

NEW DRUGS APPROVED in 2024



Healthcare professionals are encouraged to report all serious and non-serious suspected adverse drug reactions (ADRs) with the use of new drugs. Your active participation in the ADR monitoring programme will provide valuable support to the post-marketing surveillance on drug safety.

HOW TO REPORT

Please report to us as soon as you are made aware of the adverse events. You may do so by reporting online at <https://www.hsa.gov.sg/adverse-events> or download the ADR reporting form and send the completed form to Vigilance and Compliance Branch, HSA either by post or email.

WHERE TO SEND YOUR REPORT

Vigilance and Compliance Branch, Health Products Regulation Group,
Health Sciences Authority

11 Biopolis Way, #11-01, Helios, Singapore 138667
Tel: +65-6866 1111 • Email: HSA_productsafety@hsa.gov.sg

NEW CHEMICAL / BIOLOGICAL ENTITY	PHARMACOTHERAPEUTIC GROUP
Artesunate 110 mg/vial Artesunate Amivas® powder & solvent for solution for injection	Antimalarial agent (POM)
Asfotase alfa 40 mg/ml, 100 mg/ml STRENSIQ® solution for injection	Enzyme replacement therapy (POM)
Atogepant 10 mg, 60 mg AQUIPTA® tablets	Antimigraine preparation (POM)
Avacopan 10 mg Tavneos® hard capsule	Immunosuppressant (POM)
Avalglucosidase alfa 100 mg/vial Nexvazyme® powder for concentrate for solution for infusion	Enzyme replacement therapy (POM)
Capivasertib 160 mg, 200 mg TRUQAP® film-coated tablets	Antineoplastic agent (POM)
Chlormethine 160 mcg/g LEDAGA® topical gel	Antineoplastic agent (POM)
Clascoterone 1 % w/w WINLEVI® cream	Anti-acne preparation for topical use (POM)
Danicopan 100 mg & 50 mg, 100 mg VOYDEYA® film-coated tablet 100 mg + 50 mg, VOYDEYA® film-coated tablet 100 mg + 100 mg	Immunosuppressant (POM)
Deucravacitinib 6 mg SOTYKTU® film-coated tablet	Immunosuppressant (POM)
Elacestrant 86 mg, 345 mg ORSERDU® film-coated tablets	Antineoplastic agent & endocrine therapy (POM)
Elranatamab 44 mg/1.1 ml, 76 mg/1.9 ml ELREXFIO® solution for injection	Antineoplastic agent (POM)
Epcoritamab 4 mg/0.8 ml, 48 mg/0.8 ml EPKINLY® concentrate for solution for injection 4 mg/0.8 ml, EPKINLY® solution for injection 48 mg/0.8 ml	Antineoplastic agent (POM)
Etrasimod 2 mg VELSIPITY® film-coated tablet	Immunosuppressant (POM)
Filgotinib 100 mg, 200 mg Jyseleca® film-coated tablets	Immunosuppressant (POM)
Fruquintinib 1 mg, 5 mg FRUZAQLA® capsules	Antineoplastic agent (POM)
Glofitamab 1 mg/ml Columvi® concentrate for solution for infusion	Antineoplastic agent (POM)
Levamlodipine 2.5 mg, 5 mg CONJUPRI® tablets	Antihypertensive agent (POM)
Loncastuximab tesirine 10 mg/vial ZYNLONTA® for injection	Antineoplastic agent (POM)
Modified Vaccinia Ankara - Bavarian Nordic (MVA-BN, live, non-replicating) 0.5 x 10 ⁶ to 3.95 x 10 ⁶ Inf. U /dose JYNNEOS® suspension for injection	Viral vaccine (POM)
Momelotinib 100 mg, 150 mg, 200 mg Omjara® film-coated tablets	Antineoplastic agent (POM)
Mosunetuzumab 1 mg/ml, 30 mg/30 ml Lunsumio® concentrate for solution for infusion	Antineoplastic agent (POM)
Nirsevimab 50 mg/0.5 ml, 100 mg/1 ml Beyfortus® solution for injection in pre-filled syringe	Prophylactic viral specific immunoglobulin (POM)
Pemigatinib 4.5 mg, 9 mg, 13.5 mg PEMAZYRE® tablets	Antineoplastic agent (POM)
(MBC): Pneumococcal polysaccharide serotype 1 conjugated to CRM ₁₉₇ 2 mcg, Pneumococcal polysaccharide serotype 14 conjugated to CRM ₁₉₇ 2 mcg, Pneumococcal polysaccharide serotype 18C conjugated to CRM ₁₉₇ 2 mcg, Pneumococcal polysaccharide serotype 19A conjugated to CRM ₁₉₇ 2 mcg, Pneumococcal polysaccharide serotype 19F conjugated to CRM ₁₉₇ 2 mcg, Pneumococcal polysaccharide serotype 22F conjugated to CRM ₁₉₇ 2 mcg, Pneumococcal polysaccharide serotype 23F conjugated to CRM ₁₉₇ 2 mcg, Pneumococcal polysaccharide serotype 3 conjugated to CRM ₁₉₇ 2 mcg, Pneumococcal polysaccharide serotype 33F conjugated to CRM ₁₉₇ 2 mcg, Pneumococcal polysaccharide serotype 4 conjugated to CRM ₁₉₇ 2 mcg, Pneumococcal polysaccharide serotype 5 conjugated to CRM ₁₉₇ 2 mcg, Pneumococcal polysaccharide serotype 6A conjugated to CRM ₁₉₇ 2 mcg, Pneumococcal polysaccharide serotype 6B conjugated to CRM ₁₉₇ 4 mcg, Pneumococcal polysaccharide serotype 7F conjugated to CRM ₁₉₇ 2 mcg, Pneumococcal polysaccharide serotype 9V conjugated to CRM ₁₉₇ 2 mcg VAXNEUVANCE® suspension for injection	Bacterial vaccine (POM)
Ravulizumab 100 mg/ml ULTOMIRIS® concentrate for solution for infusion	Immunosuppressant (POM)
Ritlecitinib 50 mg Litfulo® capsule	Immunosuppressant (POM)
Ropeginterferon alfa-2b 500 mcg/ml BESREMi® solution for injection in pre-filled syringe	Immunostimulant (POM)
RSVPreF3 antigen 120 mcg/0.5 ml AREXVY® powder & suspension for suspension for injection	Viral vaccine (POM)
(Powder) RSV subgroup A stabilized prefusion F protein 0.06 mg/vial, (Powder) RSV subgroup B stabilized prefusion F protein 0.06 mg/vial ABRYSVO® powder & solvent for solution for injection	Viral vaccine (POM)
Selpercatinib 40 mg, 80 mg Tantrive® hard capsules	Antineoplastic agent (POM)
(Powder vial) Sotatercept 45 mg, 60 mg; Sotatercept 45 mg, 60 mg WINREVAIR® powder for solution for injection 45 mg, 60 mg; WINREVAIR® powder for solution for injection 45 mg (vial only), 60 mg (vial only)	Antihypertensive agent (POM)

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Tagraxofusp 1 mg/ml ELZONRIS® concentrate for solution for infusion 1000 mcg/ml	Antineoplastic agent (POM)
Talquetamab 3 mg/1.5 ml, 40 mg/ml TALVEY® solution for injection	Antineoplastic agent (POM)
Teclistamab 10 mg/ml, 90 mg/ml TECVAYLI® solution for injection	Antineoplastic agent (POM)
Tildrakizumab 100 mg/ml ILUMYA® solution for injection in pre-filled syringe	Immunosuppressant (POM)
Tislelizumab 100 mg/10 ml TEVIMBRA® concentrate for solution for infusion	Antineoplastic agent (POM)
Vutrisiran 25 mg Amvuttra® solution for injection in pre-filled syringe	Agent acting on nervous system (POM)
BIOSIMILAR	PHARMACOTHERAPEUTIC GROUP
Bevacizumab 100 mg/4 ml, 400 mg/16 ml AVAMAB® concentrate for solution for infusion	Antineoplastic agent (POM)
Enoxaparin sodium 2000 IU (20 mg)/0.2 ml, 4000 IU (40 mg)/0.4 ml, 6000 IU (60 mg)/0.6 ml, 8000 IU (80 mg)/0.8 ml Enoxaparin Sandoz® solution for injection in pre-filled syringe	Antithrombotic agent (POM)
Teriparatide 20 mcg/80 mcl MEGAPTH-G® solution for injection 20 mcg/80 mcl cartridge pack, MEGAPTH-G® solution for injection 20 mcg/80 mcl pen + cartridge pack	Agent acting on calcium homeostasis (POM)
NEW COMBINATION	PHARMACOTHERAPEUTIC GROUP
Dapagliflozin 10 mg, Sitagliptin 100 mg SIDAPVIA® fixed dose combination tablet 10 mg/100 mg	Antidiabetic agent (POM)
Famtozinameran, Tozinameran COMIRNATY® Original/Omicron BA.4-5 concentrate for dispersion for injection 1.5/1.5 micrograms/dose, COMIRNATY® Original/Omicron BA.4-5 dispersion for injection 5/5 micrograms/dose (single-dose vial)	Viral vaccine (POM)
Niraparib, Abiraterone acetate AKEEGA® film-coated tablets 50 mg/500 mg, 100 mg/500 mg	Antineoplastic agent (POM)
Purified diphtheria toxoid ≥ 2 IU/0.5 ml, Purified tetanus toxoid ≥ 20 IU/0.5 ml Imovax® d.T., suspension for injection in 0.5 ml pre-filled syringe	Bacterial vaccine (POM)
NEW FORMULATION	PHARMACOTHERAPEUTIC GROUP
Atezolizumab 1875 mg/15 ml Tecentriq® solution for injection	Antineoplastic agent (POM)
Bimatoprost 0.3 mg/ml LUMIGAN® preservative-free (bimatoprost ophthalmic solution) 0.03 %	Antiglaucoma preparation & miotic agent (POM)
Budesonide 4 mg NEFEGAN® modified release capsule	Antiinflammatory & Immunomodulatory agent (POM)
Omidenepag isopropyl 0.02 mg/ml EYBELIS-S® ophthalmic solution 0.002 % w/v	Antiglaucoma preparation (POM)
NEW DOSAGE FORM	PHARMACOTHERAPEUTIC GROUP
Caffeine citrate 10 mg/ml Gencebok® solution for infusion	Treatment of apnoea of prematurity (POM)
Triamcinolone acetoneide 40 mg/ml ARCATUS® Triamcinolone acetoneide suspension for injection	Ophthalmic antiinflammatory agent (POM)
NEW STRENGTH	PHARMACOTHERAPEUTIC GROUP
Enoxaparin sodium 2000 IU (20 mg)/0.2 ml, 4000 IU (40 mg)/0.4 ml, 6000 IU (60 mg)/0.6 ml Inhixa® solution for injection 2000 anti-Xa IU (20 mg)/0.2 ml, 4000 anti-Xa IU (40 mg)/0.4 ml, 6000 anti-Xa IU (60 mg)/0.6 ml	Antithrombotic agent (POM)
Nicotine 4 mg SKIIP® nicotine mini lozenge 4 mg (mint), SKIIP® nicotine mini lozenge 4 mg (cherry), SKIIP® nicotine mini lozenge 4 mg (cinnamon)	Agent used in addictive disorders (P)
Omalizumab 300 mg/2 ml Xolair® solution for injection in pre-filled syringe	Immunomodulatory agent (POM)
NEW PRESENTATION	PHARMACOTHERAPEUTIC GROUP
Adalimumab 20 mg/0.4 ml Hyrimoz® solution for injection in pre-filled syringe	Immunosuppressant (POM)
Andusomeran 0.05 mg/0.5 ml Spikevax® dispersion for injection 50 mcg/0.5 ml in pre-filled syringe, Spikevax® dispersion for injection 50 mcg/0.5 ml in single-dose vial	Viral vaccine (POM)
Beclometasone dipropionate 0.2 mg, Formoterol fumarate dihydrate 0.006 mg FOSTER® NEXThaler® inhalation powder 200 mcg/6 mcg per dose, FOSTER® pressurised inhalation solution 200 mcg/6 mcg per actuation	Agents for obstructive airway diseases (POM)
Bretovameran (previously Raxtozinameran) 10 mcg/dose, 30 mcg/dose COMIRNATY®, dispersion for injection, 10 micrograms/dose (single-dose vial); COMIRNATY®, dispersion for injection, 30 micrograms/dose (single-dose vial)	Viral vaccine (POM)
Dabrafenib 10 mg TAFINLAR® dispersible tablet	Antineoplastic agent (POM)
Omalizumab 75 mg/0.5 ml, 150 mg/1 ml, 300 mg/2 ml Xolair® solution for injection in pre-filled pen	Immunomodulatory agent (POM)
SARS-CoV-2 recombinant spike protein (Omicron JN.1) 5 mcg/dose Nuavaxovid® dispersion for injection COVID-19 Vaccine 5 mcg/dose (recombinant, adjuvanted) in single-dose vial	Viral vaccine (POM)
Thiotepa 400 mg TEPADINA® powder & solvent for solution for infusion	Antineoplastic agent (POM)
Trametinib 4.7 mg MEKINIST® powder for oral solution	Antineoplastic agent (POM)
Ustekinumab 90 mg/1 ml STELARA® solution for injection in pre-filled pen	Immunosuppressant (POM)
NEW DOSING REGIMEN	PHARMACOTHERAPEUTIC GROUP
Aflibercept 114.3 mg/ml Eylea® solution for injection	Ophthalmic antineovascularisation agent (POM)
NEW FORENSIC CLASSIFICATION	PHARMACOTHERAPEUTIC GROUP
Bilastine 20 mg BILAXTEN® tablet 20 mg (pharmacy only)	Antihistamine for systemic use (P)
NEW FLAVOURS	PHARMACOTHERAPEUTIC GROUP
Nicotine 2 mg SKIIP® nicotine mini lozenge 2 mg (cherry), SKIIP® nicotine mini lozenge 2 mg (cinnamon)	Agent used in addictive disorders (P)

POM: Prescription-only medicine

P: Pharmacy-only medicine

GSL: General Sales List